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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,180	01/05/2005	Hisao Nishikawa	029650-162	7679

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01/24/2008

EXAMINER
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BOUCHELLE, LAURA A

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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01/24/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/520,180	NISHIKAWA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Laura A. Bouchelle	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-5 and 7-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 7-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/07 has been entered.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3,4,5,19,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (US 4781691). Gross discloses a stepped needle comprising a liquid container 40 capable of holding liquid therein; an injection needle 10 having a puncture section 20 capable of piercing a living body; a proximal end section 14 having outside and inside diameters greater than said puncture section; a tapered section 18; a base body 12 supporting the needle, wherein the tapered section and the puncture section protrude from the base body. The tapered section 18 facilitates passage of the needle through the body tissue (Col. 4, lines 29) See Figs. 2 and 6. Gross further discloses that the injection needle has a liquid introducing needle section that can communicate with the liquid container. See Fig. 2. The outside diameter of the proximal end 14 is 0.64-1.3 mm, the outside diameter of the puncture section 16 is 0.46-0.64 mm, the length from the

puncture section to the tapered section is 6.4-19 mm (Col. 3, line 63 – Col. 4, line 8). The puncture resistance is inherently 7gf or less since the device has the same size and shape as applicants. Gross discloses that the tapered section 18 facilitates passage of the needle through the body tissue (Col. 4, lines 30-33).

4. Claims 1 and 4 differ from Gross in calling for the length of the tapered section to be 1.5 to 10 mm, and the tapered section to possess an outer profile forming an angle ranging from 0.5 degree to 1 degree and 20 minutes. Gross does not explicitly disclose these ranges, however Gross does disclose that the goal of the invention is to provide easy passage of the needle into human tissue. Gross achieves this goal by forming a tapered section in the needle having a small puncture resistance. Therefore, it would have been well within the skill of one of ordinary skill in the art to determine the optimal dimensions to achieve this goal. Applicant provides a graph in Fig. 8 of applicant's disclosure to provide support and criticality for the claimed ranges. However, upon close consideration, it has been determined that this graph does not render the invention non-obvious. The graph does not show that the entire claimed range has been tested, nor does it disclose the dimensions of the needle which it is tested against. It is well known that a reduced angle will provide a smaller puncture resistance, and therefore, this graph proves nothing that is not already known. In other words, the use of the claimed dimensions does not show any unexpected results. Furthermore, the length of the tapered section is merely a function of the diameter of the smaller section, the diameter of the larger section, and the angle of the incline there between.

5. Claims 7, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross in view of Hardt et al (US 5575778). Claim 7 differs from the teachings above in calling for the proximal end of the needle to include a second needle point. Hardt teaches a syringe having a needle 26 having a point at both the proximal and distal ends so that the proximal end of the needle can be inserted though the sealed septum of a container. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the needle of Gross to have a second point on the proximal end so that the needle can be inserted into a sealed container.

6. Claims 8-11, 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross in view of Peery (US 7063681). These claims differ from the teachings above in calling for the puncture section to comprise a first facet having an angle of 8.5 degrees and a second facet having an angle of 18 degrees. Peery teaches a puncturing device having a puncture section 40 having a first facet having an angle of 5-45 degrees and a second facet having an angle of 10-60 degrees to provide minimal tissue trauma during insertion (Col. 4, lines 55-61; Col. 5, lines 7-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Gross to include the two facets as taught by Peery to reduce tissue trauma upon insertion.

7. Claims 12, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross in view of Kaneko et al (US 6517523). Claims 12, 18 differ from the teachings above in calling for the cross-sectional angle formed between the ridges of the needle point to be 129 degrees.

Kaneko teaches a needle comprising a pointed tip having a cross-sectional angle formed between the ridges to be 115-135 degrees to ensure that the resistance force at the time of sticking is as small as possible (Col. 6, lines 45-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the needle of Gross to include a cross-sectional angle of 129 degrees as taught by Kaneko to ensure that the resistance force at the time of sticking is as small as possible.

***Response to Arguments***

8. Applicant's arguments filed 10/11/07 have been fully considered but they are not persuasive.

9. Applicant argues that Gross is not concerned about the configuration of the intermediate tapered portion. The examiner disagrees; Gross discloses that the tapered section 18 facilitates passage of the needle through the body tissue (Col. 4, lines 29-30).

10. Applicant further argues that this configuration is desirable as shown in Fig. 8 of applicant's disclosure which illustrates a rise in the puncture resistance with a larger angle of taper. As stated above, this graph does not render applicant's invention non-obvious. This graph fails to show that the entire range was tested, nor does it disclose the angle of the taper which it was tested against. It is well known that a smaller angle of taper will produce a lower puncture resistance, hence the widespread use of tapered needles. Therefore, the graph, as well as the rest of applicant's disclosure fails to show that the claimed ranges are non-obvious and not the result of routine experimentation.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle  
Examiner  
Art Unit 3763

